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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,386

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Michael L. Garrison

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,386	<b>Applicant(s)</b> GARRISON ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-8 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-7,15-17 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 8, 11-14, 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2007 has been entered. Claims 1-2, 4-8, and 11-21 are pending in the application. Claims 5-7, 15-17, and 19-21 are withdrawn from consideration.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by **Shaknovich** (U.S. Patent No. **5,807,398**).

Claims 1-2: Shaknovich discloses a method for delivering and deploying an expandable intraluminal device **3a**, providing a delivery system comprising an elongate member **1** having proximal and distal ends and defining a lumen, the delivery system

further comprising an ancillary delivery device **8** at least partially disposed in the lumen and having a means for spacing a portion of the elongate member from a wall surface of a body vessel **10**, and the expandable intraluminal medical device **3a** circumferentially disposed about a portion of the elongate member **1** (Figure 1). The distal end of the elongate member **9** is inserted into a body vessel **10**, and the distal end of the elongate member **9** is advanced through the body vessel to the desired point of treatment **11** (Figure 2). A portion of the elongate member is spaced from a wall surface of the blood vessel at a point distal to said expandable intraluminal medical device **3a** by activating the means for spacing **8** (Figure 2), wherein spacing a portion of the elongate member includes the expandable intraluminal device, and the expandable intraluminal medical device is deployed from the elongate member while the elongate member has been spaced from a wall surface of the body surface, again by the means for spacing **8** (Figure 5). Lastly, the elongate member is withdrawn from the body vessel (col. 4, lines 55-58).

Claim 8: Shakhovich discloses the delivery system further comprises a sheath ("protective sheath") **13** circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal medical device comprises retracting the sheath from a position about the expandable intraluminal medical device (Figure 6; col. 6, lines 3-4, col. 7, lines 43-49)

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Kirkman** (U.S. Patent No. **6,071,263**).

Claims 4 and 11: Shaknovich discloses the claimed invention except for the means for spacing comprising a basket formed from four wires having expanded and collapsed configurations and the step of activating the means for spacing includes retracting the sheath from a position about the means for spacing.

Kirkman discloses the means for spacing comprising a basket **9** formed from four wires **12** and having expanded and collapsed configurations (Figures 2A-2B and col. 8, lines 15-19). Also, Kirkman discloses the step of activating the means for spacing includes retracting the sheath from a position about the means for spacing (col. 8, lines 10-19). Shaknovich does envision using a nitinol wire as an ancillary means of expansion (col. 9, line 64 to col. 10, line 6), and it would have been obvious to one of ordinary skill in the art to modify Shaknovich using a basket formed from four wires and using a retractable sheath about a means for spacing, as taught by Kirkman, to more efficiently contact the circumference of the blood vessel while not obstructing the fluid flow through the blood vessel and not causing clots (col. 7, lines 22-30) as well as to

protect the blood vessel from the means for spacing until expansion and to avoid the need for a second mechanism to expand the means for spacing.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 12: Shaknovich discloses the claimed steps except for the expandable intraluminal medical device comprising a venous valve.

Pavcnik et al. teach an intraluminal venous valve **43** that is deployed within the blood vessel and exerts force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6, page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the device of Shaknovich, since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

7. Claims 13-14 are U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Levine et al.** (U.S. Pub. No. **20040087965**).

Claims 13-14: Shaknovich discloses the claimed invention (see paragraph 3 above), except for the means for spacing, or ancillary device, comprising a basket formed from at least two wire members and having expanded and collapsed configurations such that

it is movable within a lumen of an elongate member and may be distally advanced beyond an expandable intraluminal medical device, and the two wire members comprising flat wire.

Levine et al. teach an ancillary delivery device having a basket **104** in the collapsed configuration when disposed in a first lumen **114** of **102** and is in the expanded configuration when not disposed in the first lumen (Figure 4F, page 3, paragraphs 37 and 40). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the means for spacing in Shaknovich by providing a basket that collapses into a first lumen and is expanded when not disposed in a first lumen, as taught by Levine et al., since it was known in the art that expandable and collapsible mechanisms are often used in deploying devices since they are readily actuated and withdrawn by the surgeon and effectively facilitate deployment of intraluminal devices.

In addition, Levine et al. teach wire members **104** comprising flat wire (page 3, paragraph 37). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Shaknovich by using flat wire, as taught by Levine et al. since it was known in the art that flat wire would provide more surface area and therefore better contact or engagement with surfaces.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Levine et al.** (U.S. Pub. No. **20040087965**), as applied to Claim 13 above, and further in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 18: Shaknovich and Levine et al. disclose the claimed device except for the expandable intraluminal device comprising a prosthetic venous valve.

Pavcnik et al. teach an intraluminal venous valve **43** that is deployed within the blood vessel and exerts a force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49; page 1, paragraph 6; page 6, paragraph 68; page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to Shaknovich and Levine et al., since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 13 and 14 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments filed 10/29/2007 have been fully considered but they are not persuasive.

11. Applicant generally argues that Shaknovich discloses a delivery system for a stent wherein the delivery system is spaced from the vessel while before deployment of

Art Unit: 3731

the stent, and therefore are two separate steps, which does not read on the recited limitation that the step of "deploying said expandable intraluminal medical device from the elongate member" occurs "while the elongate member is being spaced from a wall surface of the body vessel." However, as maintained above, the Shaknovich discloses spacing a portion of the elongate member **5** from a wall surface of the body vessel at a point distal to said expandable intraluminal medical device by activating the means for spacing **8** (see Figure 2), and then deploying said expandable intraluminal medical device **3b** from the elongate member while the elongate member is being spaced from a wall surface of the body vessel by the means for spacing **8** (see Figure 5), and therefore the invention of Shaknovich reads on the recited method steps of Claim 1.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731